

28. (New) The method of claim 21, further comprising:  
administering relaxin to the organism; and  
allowing the relaxin to contact the receptors for a period of time and under  
conditions such that the receptors are activated by the relaxin.

**REMARKS**

Claims 21-28 are now pending in this application.

Original claims 1-20 have been canceled and new claims 21-28 were added to more particularly point out and distinctly claim the invention. The newly added claims are fully supported within the originally filed application. Support for new claim 21 can be found throughout the specification including the language contained with previously pending now canceled claim 4 with respect to the specific language describing relaxin like factor. Methods of administering relaxin like factor to an organism such that it binds to a relaxin like receptor are described throughout the specification such as at page 6, lines 2-6 and within the specific examples provided. Specific information regarding the time and conditions under which relaxin like factor can bind to the receptors are provided within the specific examples beginning on page 26 and within the various references cited throughout the application and incorporated by reference into the application.

New claim 22 is supported at numerous places in the specification including page 6, lines 11-16 and within the examples such as the example 6.2 beginning on page 32 of the specification.

New claim 23 is supported within the publications cited and within the examples provided such as the methodology described beginning at page 26, line 27.

New claim 24 is supported at numerous places in the specification including the description provided at page 11, lines 25-35.

New claim 25 is supported in the examples such as the example 6.5 beginning at page 36, line 28. Similarly, new claims 26 and 27 are supported in the examples such as example 6.6 beginning in the specification at page 38, line 8. New claim 28 is supported in the specification such as at page 9, lines 23-26. No new matter has been added.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 4-6 and 14-19 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter not described in the specification in a manner which would enable one skilled in the art to make and use the invention. The rejection is traversed as applied and as it might be applied to the presently pending claims.

It is applicants position that the rejection has been overcome by the cancellation of previously pending claims and the addition of new claim 21. The specification clearly teaches that relaxin like factor does bind to and activate relaxin receptors. Further, specific examples are provided in the specification where relaxin like factor is shown to bind to relaxin receptors and specifically shown not to be particularly competitive with respect to relaxin itself except when relaxin is contained in very high concentrations. Further, applicants have described and those skilled in the art are aware of conditions under which a protein such as relaxin like factor can be allowed to result in the activation of receptors. Clearly, the receptors could be present on any organism including sperm, cells, cells present in tissue and tissue present within a multi-cellular organism.

The precise effect of the relaxin like factor in treating an organism such as a mammal has not and need not be focused on in the claims of the present application. Applicants have invented a method based on the unexpected discovery that isolated relaxin like factor protein binds specifically to relaxin receptors and not to insulin receptors (see the specification at page 9, lines 8-13). These results are unexpected. Specifically, the deduced amino acid sequence of relaxin like factor would have predicted an opposite result because the critical two arginine residues separated by three amino acids in the relaxin like factor sequence is offset towards the C-terminal of the B chain by exactly one turn of the helix. Accordingly, although relaxin like factor projects the argenines at nearly right angles away from the molecular surface in the manner of relaxin, one would expect that shifting the whole receptor-binding site would present quite a different binding environment to the receptor. This is described in the specification such as at page 9, lines 14-22. Further, applicants have specifically found that relaxin like factor binds to the relaxin receptor but does not appear to competitively bind to the relaxin receptor via the relaxin except when the relaxin is present in high concentration. Rather, applicants found that relaxin like factor appears to stimulate the

relaxin response. This is described in the specification such as at page 9, lines 23-27. Further, the results provided within the examples show that relaxin like factor binds to and stimulates relaxin receptors and is not competitive via the relaxin.

As indicated in the specification and claimed in dependent claim 22 the relaxin like factor may be attached to a detectable label. Such would make it possible for researchers to specifically study where relaxin receptors are present and the concentration of such receptors on different cells in different tissues. Accordingly, the method as claimed is useful and enabled within the meaning of 35 U.S.C. §101 and §112, first paragraph. In view of such reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 4-6, 14-15 and 17-20 were rejected under 35 U.S.C. §112, second paragraph. The rejection is traversed and as it might be applied to the presently pending claims.

In essence, the rejection argues that the previously pending claims were indefinite due to the use of terms such as "conditions susceptible to treatment with relaxin." These and other terms objected to have been eliminated from the present claims. The invention now claims a simple straightforward method whereby relaxin like factor is administered to an organism which expresses relaxin receptors. Cells and sperm are clearly organisms and the administration of relaxin like factor to such is clearly exemplified within the specification. Further, the invention now claimed indicates that the relaxin like factor is allowed to remain in contact with the receptors for a period of time and under conditions such that the receptors are activated. Specific conditions for obtaining activation of receptors are specifically recited within the examples of the specification beginning on page 26. Further, the relaxin like factor itself is specifically described within the claims. Accordingly, the invention is believed to be particularly pointed out and distinctly claimed within the meaning of 35 U.S.C. §112, second paragraph. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

### CONCLUSION

The original claims 1-20 have been canceled and new claims 21-28 have been added. Support for the new claims has been pointed out. The invention is now simply claimed as a method whereby relaxin like factor is administered to an organism which expresses relaxin receptors and allowed to remain in contact with the receptors in a manner so as to activate the receptors -- see claim 21 and the relaxin like factor may be labeled -- see claim 22. Specific examples where such has been carried out with different organisms are provided in the specification. Accordingly, the objections and rejections under 35 U.S.C. §112, first and second paragraphs are believed to have been overcome and allowance of the application is respectfully requested.

This response is being filed with a petition and petition fee for a two month extension of time. In the event other fees are required applicants petition for any required relief and authorize the Commissioner to charge the cost of such petitions to our Deposit Account 50-0815.



Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: Sept 15, 2000

By: \_\_\_\_\_

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